**Committee for Socio-economic Analysis (SEAC)**

**Response to comments on the SEAC draft**

**Opinion**

**on the Annex XV dossier proposing**

**restriction on**

**Bisphenol A; 4,4'-isopropylidenediphenol**

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| **Substance name** | **EC number** | **CAS number** |
| **4,4'-isopropylidenediphenol (Bisphenol A or BPA)** | 201-245-8 | 80-05-7 |

**4 December 2015**

Comments on the SEAC draft opinion

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 226 | **Date/Time:** 2015/11/10 11:10  **MS name:**  Germany  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  The German CA strongly supports the SEAC conclusion that the proposed restriction is affordable and adequat from a societal point of view. Thus, we share the opinion that the identified risk, arising from the continious use of Bisphenol A in thermal papers, for a small proportion of the society can and should be minimized with negligible costs for the whole society.  Furthermore, we would like to point out that the proposed restriction has additional benefits, even though they cannot be quantified, from an environmental point of view since the open use of Bisphenol A in thermal papers is considered to be one major exposure pathway for the environment. Taking into account these environmental benefits the proposed restriction would be even more adequate and affordable.  Finally, the German CA supports the SEAC view that other Bisphenols like Bisphenol S cannot be considered to be suitable substitutes for Bisphenol A owing to their evenly concern rising hazard profiles. | |
| **SEAC Rapporteurs response:**  Thank you for the comments. For clarification we would like to point out that, the SEAC conclusion does not state that the proposed restriction is “adequate” from a societal point of view; neither does the opinion state that the identified risk should be minimised with negligible costs to society.  No assessment of environmental benefits was undertaken by the DS, and SEAC has no information about possible environmental risk reductions compared to the alternatives. In the lack of evidence of any benefits to the environment from the proposed restriction, SEAC does not find it appropriate to take this into account. | |
| 234 | **Date/Time:** 2015/11/12 13:49  **MS name:**  Sweden  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  1.The Swedish Chemicals Agency has investigated the preconditions for implementing a national ban on bisphenol A in receipts (KemI 2012). It was found that many companies prefer a harmonised EU-policy in the area. The conclusion made by SEAC that the action is justified on an EU wide basis, is thus agreed upon by the Swedish Chemicals Agency.  In the above mentioned study (KemI 2012) it also became evident that many retail companies already have substituted BPA in thermal papers, or are in a process of such a substitution. A decision on regulation of BPA in thermal paper would therefore probably not be found controversial by the retail industry.  2.The Swedish Chemicals Agency supports the conclusion of the draft SEAC opinion that transition from BPA to BPS, or other bisphenols, may not be beneficial, and a future restriction including BPS (and other bisphenols) would be necessary. In this regard it can be noted that several actors in retail industry in Sweden prefer that other bisphenols are also included in future regulations (KemI 2012).  3.The Swedish Chemicals Agency appreciates that the draft SEAC opinion emphasises distributional and affordability considerations. Indeed, as mentioned in the draft opinion, the cashier progeny is a vulnerable group that might be harshly affected by the identified health impacts. The conclusion that this group can be protected by a restriction, and that the costs for the restriction will be shared between all consumers/citizens in the EU is very appealing.  4.RAC has concluded that BPA has low-dose effects with non-monotonic dose-responses. This complicates the quantification of the adverse health effects of exposure. What implications does this finding have on the outcome of the current socio-economic analysis and in terms of uncertainties connected with it? A discussion on how well the used socio-economic analysis methodology is suitable for compounds such as BPA would be valuable and should therefore be included in the SEAC opinion.  5.Page 12: The assumption made by the Dossier Submitter, that the market for thermal paper will increase by 5-7 % per year, can be questioned as the digital technique with electronic receipts is growing (The Danish EPA 2014). In that case, the substitution cost is likely to be overestimated. Also, SEAC’s assumption that the market for thermal paper will stay constant, is not strengthened in the SEAC draft opinion. Based on The Danish EPA (2014), that the market for electronic receipts is growing, it is also likely that that assumption is overestimated.  In addition, if the price difference between the non-bisphenol alternatives and BPA will persist over time, which is assumed in the opinion, a reduction (compared to baseline) of the total consumption of thermal paper can be expected (assuming that the price elasticity of demand for thermal paper is <0).Thus, also for this reason the identified costs may be overestimated.  6.Page 12: The assumption made by SEAC that the price difference between BPA and non-bisphenol alternatives will persist over time (i.e. to year 2030) seems highly conservative and may lead to an overestimation of the costs.  References:  KemI (2012) Bisfenol A i kassakvitton – rapport från ett regeringsuppdrag. Kemikalieinspektionen Rapport Nr 4/12. http://www.kemi.se/global/rapporter/2012/rapport-4-12.pdf  The Danish EPA (2014) Alternative technologies and substances to bisphenol A (BPA) in thermal paper receipts. Environmental Project No. 1553, 2014. http://www2.mst.dk/Udgiv/publications/2014/03/978-87-93178-20-5.pdf | |
| **SEAC Rapporteurs response:**  Thank you for the comments. Our responses to each of the points are as follows:  1. Based on the risks for workers, SEAC found that EU wide action was justified. We appreciate the support for this conclusion.  2. SEAC followed the advice of RAC in suggesting that BPS cannot be considered a suitable substitute.  3. We appreciate the support for our consideration of distributional and affordability issues.  4. Section 1.1.8.5 Non Monotonic Dose Response (NMDR) of the opinion of RAC refers to EFSA (2015). EFSA considered that the available data do not provide evidence that BPA exhibits a NMDR. However, RAC is of the view that the available data on these effects does not allow a quantification of the dose-response relationships.  In the absence of any robust dose-response relationships, the original socio economic analysis performed by the Dossier Submitter could no longer be substantiated, and thus the remaining options for SEAC to assess the proportionality were limited. Rather than rejecting the proposal due to the lack of demonstration of proportionality arising from these issues, SEAC chose to perform a break-even analysis (which does not require dose response relationships) to investigate whether proportionality could be justified.  5. Thank you for the information from Danish EPA (2014), which we have taken into account in the final version of the opinon. However, it should be noted that the provided documentation states that the market for thermal paper is increasing, which means that the costs are likely to be underestimated.  If the price of thermal paper increases due to the rise in costs, demand may fall (if and how much depends on the price elasticity). However, it is not clear that the prices will rise, since it is an international market, and the price is not necessarily set within the EU alone. We can thus not conclude whether a rise in price will occur, and whether there will likely be a corresponding fall in demand.  6. The assumption made by SEAC concerning the price difference between BPA and non-BPA alternatives is based on evidence provided by the Dossier Submitter and the ECHA secretariat. No contradictory evidence has been made available to SEAC, such that we do not understand the basis upon which it is claimed that the assumption is highly conservative. | |

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| 248 | **Date/Time:** 2015/11/13 17:44  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  European Thermal Paper Association (ETPA)  **Org. country:**  Switzerland  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  Summary  For ETPA members there is currently no other option except to use BPS as an alternative dye developer, due to restrictions in the technical implementation and safety of supply. All currently known dye developers, and their alternatives, are the result of more than 30 years of technological development. There are, to date, no alternatives in the pipeline that could be easily used to substitute BPA and BPS. In addition, the most promising phenol-free alternative, Pergafast, is protected by a patent that results in a monopolistic supply situation, which would be a critical factor for the thermal paper manufacturing industry.  Decision makers should be aware that this restriction is based on a vague risk which is not clearly quantifiable; a negative cost-benefit ratio, where the costs outweigh the health benefits by far; and that the main argument from SEAC is that the costs for the individual consumer is rather small. If the outcome of the SEA does not have any influence on the decision making process by the ECHA committees and the European Commission, then the whole assessment process is put in question.  In summary, it remains extremely questionable to implement this restriction for a substance where 1) the risk is low (RCR = 2), even under circumstances where risk characterisation is based on worst-case assumptions and overall low confidence in available data; 2) the socio economic benefits are negative (in order of a magnitude); 3) the supporting argumentation only relies on the social acceptance due to low costs per citizen; and 4) the only feasible drop-in alternative is BPS where the health benefits are estimated to “be zero” by SEAC.  For more information please see the attachment provided. |
| **SEAC Rapporteurs response:**  Thank you for the comment. SEAC note the concerns regarding Pergafast. The opinion concludes that benefits are unlikely to outweigh the costs. We agree that a key argument in support of the restriction relies on affordability and distributional concerns. SEAC cannot say from an analytical perspective whether such considerations should override the likely unfavourable cost-benefit assessment of the proposal. However, SEAC wanted to raise these aspects in its opinion for the benefit of the decision maker. |
| 277 | **Date/Time:** 2015/11/16 17:23  **Type:** International NGO  **Org. type:**  International NGO  **Org. name:**  CHEM Trust  **Org. country:**  United Kingdom  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  CHEM Trust welcomes the opportunity to comment on the Committee for Socio-Economic Analysis (SEAC) draft opinion on restrictions on Bisphenol A (BPA) in thermal paper.  SEAC’s draft opinion concludes that the proposed restriction of BPA in thermal paper is unlikely to be proportionate. We consider that this analysis is flawed, with important assumptions and omissions, noted in the bullet points below.  In addition, in our view SEAC’s analysis should be limited to socio economic impacts. The assessment of proportionality is a political decision which needs to be taken by the EU Commission, with EU Member States.  CHEM trust agrees that affordability and distributional equity (i.e. who gains and who loses) are important, and we strongly believe that current society should not knowingly be permitted to impart costs on the next generation. Therefore, on this argument alone, this restriction should be adopted.  It is worth noting that SEAC accepts that the financial cost of the BPA restriction is low, around 10-20 cents per year (7-14 pence/year) per consumer; this is clearly affordable.  Comments on the analysis:  • Re Alternatives (p6): Concerns about BPA being replaced with BPS, which may have similar adverse health effects as BPA, should not prevent action on BPA. A restriction on BPA will send a strong signal that bisphenols in general are not wanted by regulators and will lead to intensified development of bisphenol-free alternatives.  • Non-Point of Sale workers are ignored in the benefits assessment: SEAC notes that the scope of the restriction includes both thermal paper used for Point of Sale (POS) and non-Point of Sale (non-POS) applications (eg. lottery tickets, self adhesive labels) and calculates the costs to industry of switching away from BPA thermal paper in all these sectors. However, despite POS applications only accounting for only 50-65% of the BPA consumed in thermal paper, SEAC has only looked at the benefits to POS workers (eg. the children of cashiers), ignoring potential benefits to other workers including distribution industry, lottery, and office workers (eg. handling fax paper and self adhesive labels).  • Exposed female workers, page 14: In order to do a ‘break even’ analysis SEAC looks at a single adverse effect in isolation, changes to the mammary gland of female offspring of cashiers, and puts a cost on this. They calculate 10,280 daughters of cashiers would need to be adversely affected for health costs to balance the costs to industry. SEAC considers that such high numbers of female offspring harmed is unlikely, but CHEM Trust would challenge this because:  i) the number of female workers at risk has probably been under-estimated as SEAC did not include lottery ticket sellers, secretaries and distribution workers  ii) we would question the evidence behind the assumption that there are only 180,000 cashiers throughout the whole EU who might be pregnant or breastfeeding and so only 79,000 unborn female offspring who might be exposed. SEAC assume that only 50% of these (39,500) might be at risk because of exceedance of the DNEL.  • Assumptions and potential biases in the break-even analysis, Table 8, page 26: SEAC does note that it has missed non-POS workers in its calculation of the benefits. However it considers the result isn’t biased because the number they are using (180,000) may include other workers employed in retail sales, so the number in contact with receipts and tickets might be 40-80% lower that this. CHEM Trust disagrees, as our view is that the likely exposed population at risk has been underestimated (see above), so benefits will be underestimated.  • Cost of the mammary gland changes in the population at risk, p14: Even if the SEAC figure for the number of female babies potentially at risk was correct (39,500), CHEM Trust considers it feasible that 26% of these offspring might develop mammary gland changes due to in-utero exposure. Moreover, based on animal studies, CHEM Trust would argue that it is feasible there would be a 5.5% or even higher breast cancer incidence rate in this population. SEAC’s assumptions that such levels of harm in the population are unlikely are not warranted in our view, noting that the Risk Assessment Committee (RAC) concluded a risk for workers.  • Mammary gland changes, p14, footnote: CHEM Trust would query the statement that some changes to the architecture of the mammary gland due to in-utero exposure to BPA are reversible.  • Potential for multiple effects due to BPA exposure in utero, page 15: SEAC looks at the costing of potential multiple health endpoints, allocating 20% of the total health costs to each of the following potential effects: mammary gland, immunotox, neurobehaviour, reprotox and metabolic. However, SEAC dismisses this scenario by noting that RAC emphasised that “it would be exceptionally unlikely that all of the incidence rates.. would occur concurrently in the population at risk due to exposure of workers to BPA from thermal paper”. However, while CHEM Trust might agree that it is unlikely that all effects would occur simultaneously, we find it highly plausible that one or more additional effects might be concurrent in the population, although not in the same individual. For example, immunotoxic effects or metabolic effects in the male and female offspring of cashiers along with effects on the mammary gland. RAC should have been asked what was the likelihood of one or more effects manifesting in the in-utero exposed children of cashiers.  • Furthermore, CHEM Trust considers that in the allocation of costs to other potential end-points, many end-points and therefore costs have not been included. For example, the costs of skin allergies have not been included, only the cost of food and respiratory allergies. |
| **SEAC Rapporteurs response:**  Thank you for the comments. We would make the following observations and responses on the information provided. The SEAC opinion provides an assessment of proportionality of the restriction in the analytical sense of comparing benefits and costs. As such we do not have a problem with the contention made in the comment that proportionality is a political decision – nevertheless, we are talking about different things – one (the SEAC opinion) relates to the comparison of socioeconomic benefits and costs as defined under the welfare theoretic approach underpinning cost-benefit analysis, whilst the other (as considered by the comment) concerns socio-political acceptability. As underlined in the opinion, SEAC does not conclude on proportionality in terms of socio-political acceptability, and we agree that this is and should be a political decision.  We appreciate the support for considering affordability and distributional equity in the opinion. We would also note that whilst the use of BPA in thermal paper may impart costs on the next generation, the restriction imparts costs on the current generation. The point of the analytical approach taken is to assess and compare these respective costs.  We agree that the restriction costs per individual are low and hence can be considered affordable. However, this is a rather weak criterion in terms of assessing the net welfare of society as a whole.  Regarding alternatives, SEAC has followed the advice of RAC in suggesting that BPS cannot be considered a suitable substitute. We also agree that this should not prevent a restriction on BPA, and this is the reason for why SEAC has evaluated the restriction under the assumption that the actors will choose other alternatives in case a restriction on BPA will be implemented (either by choice or by a following restriction on BPS).  Regarding non-point of sale workers, the opinion highlights the uncertainties associated with the population at risk and determines that (taking into account the non-inclusion of non-point of sale workers) the population used in the analysis is not biased in any particular direction. CHEM Trust asserts that the likely exposed population has been underestimated but offers no evidence as to how it has reached this conclusion.  Regarding the number of female offspring required to be adversely affected, we note the concerns of CHEM Trust, but would highlight the following points in response: 1) as just discussed previously, the population at risk estimate is not considered to be biased; 2) we do not understand on what basis CHEM trust questions the evidence that there are 180,000 cashiers who might be at risk. The Dossier Submitter initially used a lower estimate for the number of cashiers in the EU, but following the recommendation by SEAC this was changed to include all kinds of sales workers (even though this may lead to an overestimation of the actual population at risk). CHEM trust asserts that the evidence is flawed but offers no evidence for a better estimate of the actual number of cashiers in the population.  Regarding the cost of the mammary gland changes in the population at risk, there appears to have been a misunderstanding about the nature of the break-even analysis, which considers the number of cases that would be necessary for the restriction to ‘break-even’ rather than representing the number of actual cases arising from exposure in the population. SEAC has amended the opinion in an attempt to clarify. Moreover, we do not understand the basis and evidence upon which CHEM Trust argue that it is feasible there would be a 5.5% breast cancer incidence rate – animal studies do not provide grounds to allow such an extrapolation to be undertaken (otherwise RAC and the DS would have concluded accordingly).    Regarding reversible changes in mammary gland architecture, SEAC are following the advice of RAC.  Regarding potential multiple effects due to BPA exposure in utero, there appears to have been a misunderstanding about the nature of the analysis undertaken. SEAC does not assume that all the effects are concurrent within one individual, but the analysis requires that the effects are concurrent within the population at risk. This is also what was presented to RAC. Another point we would like to highlight is that assuming lower incidence rates (=costs) for one endpoint would immediately raise the necessary incidence rate for one or more of the other endpoints (and in some cases incidence rates for the effects would need to be greater than 100%).  Regarding allocation of costs, there appears to have been a misunderstanding about nature of the analysis – the break-even analysis implicitly takes all possible effects into account in allocating costs as explained in the opinion. |
| 278 | **Date/Time:** 2015/11/16 17:37  **MS name:**  Denmark  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  The Danish Competent Authorities for REACH & CLP welcome that both RAC and SEAC conclude that action regarding Bisphenol A in thermal paper is justified on an EU wide basis which is fully supported by the Danish EPA.  The Danish EPA notes that SEAC in its draft opinion concludes that the proposed restriction is unlikely to be proportionate from a normal cost-benefit perspective. However, we also note that neither RAC, nor SEAC is considering that cashiers are also exposed to BPA during their normal life as consumers (incl. exposure from food contact materials), which adds to the risk to the cashiers.  Another approach when evaluating impacts of risks related to chemicals is the burden of disease concept. A number of scientists have estimated the burden and disease costs of exposure to endocrine disrupting chemicals in the EU (Leonardo Trasande et al, and Juliette Legler et al). Instead of using the RCR approach, they base their estimates on epidemiologic evidence. Using this approach also marginal overweight and obesity effects among the general public are taken into taken account when evaluating impacts of a restriction.  Looking at the assumptions for valuation factors, mentioned in table 7 of the opinion, and used in the evaluation of the proportionality, The Danish EPA has the following comments:  - Metabolic effects: The value is calculated as the average of cost for cholesterol and body weight. The value of overweight is assumed to be €4,131 per case avoided (BD p. 489). The last one is based on a valuation from Brown III (2007) covering only medical treatment and productivity loss. However, no welfare element was included. One way to do this would be to include valuation of lost QALYs, which in the same article (in line results in with other studies) is calculated to be 8.55 QALY per obese person. According to Muennig et. al (Muennig P, Lubetkin E, Jia H, Franks P 2006 “Gender and the burden of disease attributable to obesity”. American Journal of Public Health 96:1662) the average QALY per case of overweight is 1.7, and the average QALY per case obesity is 5.8. The SEA guidance mentions that the values of a QALY can be compared to the value of a statistical life. Reference values between €20,000 and € €50,000 per QALY are mentioned in literature. Taking the lowest value the QALY gain of avoiding one case of overweight would be 34,000 €. Thereby the value would be 10 times higher than used in the calculations. Furthermore for the direct costs, other studies show significant higher costs. Finkelstein (2014, lifetime direct medical costs of childhood obesity) mentions direct costs of 12,660 – 19,080 $ (2012 price level) as a lifetime medical cost for an obese 10 year old child.  - Immunotox – Medium value is estimated to 1987€ per incidence. The valuation factor for immunotox was constructed as a simple average of a valuation factor for food allergies (Gupta et al. 2013) and a derived valuation factor for respiratory allergy.  Food allergy: Reference to Gupta et al showing annual costs of $ 4184. However, if the relevant period is 10 years, the total would be $ 36,522 (if a calculation rate of 4% is used) similar to 34,000 € (costs are medical costs, out-of pocket costs (special foods) and opportunity cost for caregiver). If discounting is taken into consideration: € 23,800. Also here, welfare loss is not taken into account.  For respiratory allergy the value is derived from a meta study on medical costs (Simoens 2012) and a single study on societal costs of respiratory allergy (Suijkerbuijk et al 2013). The Danish EPA notes that the last mentioned study only includes direct costs of which 90% relates to medication. No sickness absence was included and no reliable data were available concerning productivity losses for this condition, but this should be me interpreted as that this would not occur. The same seems to apply for the studies mentioned in Simoens (2012). Furthermore, no information on welfare loss for having to deal with the problems is included.  • Discounting. A number of the effects are considered occur after many years and therefore the discounting factor has great influence on the outcome. We acknowledge that a low discounting rate is used, where the value of preventing a fatality has a constant utility value. However, the values are still 2-3 times lower than if discounting were not taken into account.  Therefore, We welcome that SEAC has ventured into estimates of affordability aspects, which from a societal and policy point of view is of considerable importance. In this aspect, we note the very low annual costs of introducing the proposed restriction, i.e. only 4-9 Euro per cashier corresponding to 0.1-0.2 Euro per EU-citizen.  It is also welcomed that SEAC is describing the distributional equity, i.e. identifying those sub-populations that might be affected by the continuous use of BPA in thermal paper at the expense of a cost for the society at large, as this is important information that can guide the subsequent policy decision by the Commission and the Member States.  Finally, although SEAC of course can have an opinion on the proportionality of the proposed restriction, SEAC should rather, on a scientific basis, assess the “proportions” of the costs and benefits of the different risk management options and of the alternatives available to the use of the substance considered, and thus provide the basis for discussions at policy level on the proposed restriction. In the end, the assessment of the proportionality of the restriction proposal is, in our view, a policy issue that should merely be addressed by the Commission in its proposal for deciding on the restriction proposal and by the Member States in their deliberations in the REACH Committee |
| **SEAC Rapporteurs response:**  We are grateful for the comments received. We would like to make the following responses and observations.  In response to the comment related to risks to cashiers, SEAC needs to base its assessment on risks established by RAC. Regarding the burden of disease approach noted in the comment, we would point out that such a disease burden approach was originally proposed by the Dossier Submitter. As discussed in the opinion, RAC is of the view that the available data on these effects does not allow a quantification of the dose-response relationships and thus the disease burden approach was not appropriate. The basis for the Trasande et al. (2015) and Legler et al. (2015) publications is not consistent with the view of RAC. RAC nor the Dossier Submitter used epidemiological studies as a basis to determine dose-response relationships.  Regarding Metabolic effects, we note the comments on the lack of a welfare element and have now included some consideration of this in the opinion. Likewise, the similar comments concerning immunotox effects were noted. Adjustments were made to the immunotox valuation factor, to allow for a 10-year average course of disease, and an amendment included in the opinion to reflect the uncertainty concerning the values used.  Regarding affordability an distributional equity, we appreciate the support for our consideration of this aspect.  Regarding the comment concerning proportionality, we refer to our response to CHEM Trust above. |
| 284 | **Date/Time:** 2015/11/16 19:30  **Type:** National NGO  **Org. type:**  National NGO  **Org. name:**  Breast Cancer UK  **Org. country:**  United Kingdom  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  Breast Cancer UK is dedicated to the prevention of breast cancers by reducing public exposure to the carcinogenic, hazardous and hormone disrupting chemicals which are routinely found in the environment and everyday products. We welcome the opportunity to comment on the Committee for Socio-Economic Analysis (SEAC) draft opinion on restrictions on Bisphenol A (BPA) in thermal paper.  Breast Cancer UK support fully the restriction proposal of bisphenol A (BPA) in thermal paper, in order to reduce worker, consumer and environmental exposures. Numerous studies, including many cited in the committee for risk assessment (RAC) report, have demonstrated that BPA alters mammary tissue, including changes which are likely to increase breast cancer risk. The restriction proposal aims specifically to address the risks for human health of pregnant woman and their unborn children. As documented in the RAC report, studies have shown fetal exposure to BPA at environmentally relevant doses alters mammary glands in animals, and is likely to affect human mammary glands which may result in breast cancers in later life. Evidence also suggests BPA exposure affects the female reproductive system, metabolism, obesity, the brain and behaviour and the immune system.  Breast Cancer UK believe the restriction should be extended to other bisphenols which may be used as BPA substitutes, as these are also suspected of being similarly toxic and damaging to human health and the environment. The RAC considered imposing a ban on all bisphenols in thermal paper, but dismissed this option due to lack of toxicology data. We support fully SEAC’s suggestion that a restriction proposal on BPS should be carried out if a restriction on BPA is implemented.  Breast Cancer UK is disappointed that SEAC consider the proposed restriction on BPA in thermal paper “unlikely to be a proportionate measure in terms of standard benefit cost considerations”. We disagree with this strongly, and do not believe a “break even level of benefits” on which the conclusion is based is an appropriate way to assess potential breast cancers and other health outcomes associated with BPA. SEAC acknowledge that “adverse health effects arising from exposure to BPA can occur to the descendants of exposed female cashiers and consumers”, that “action to address risks to human health aimed at workers is justified on an EU wide basis” and “that the proposal is implementable, enforceable and manageable”. Despite this, SEAC has described the restriction as unlikely to be proportionate, based on calculations of excess risk estimates of specific health outcomes versus substitution costs.  SEAC argues the largest benefits are likely to be achieved if substitution from BPA is to a non-bisphenol alternative - which we agree strongly with - and estimate the corresponding costs would be €43 - €86 million per year. If the costs are transferred into increased prices of consumer goods, the amount per EU-citizen will amount to ca. €0.1 – €0.2 per person per year. The draft opinion states that in order for the health benefits of the restriction to offset the total costs of transition to a non-bisphenol alternative the hypothetical absolute risk reduction for the given adverse effects would have to be (medium cost) 5% having mammary gland changes, 8% having immunotoxicity-related allergies, 2% having neurobehavioral effects, 6% experiencing adverse reprotoxic effects and 4% having hypercholesterolemia or weight gain. The relatively trivial costs of removing BPA are equated with potentially enormous costs to human health, including probable increases in breast cancer incidence. Furthermore, this type of cost-benefit analysis does not appear to take into consideration the personal costs to those suffering from breast cancers and other health impacts associated with BPA exposures.  SEAC estimate that 39,500 female babies may be at risk following in utero exposure from BPA in thermal paper. If a quarter of these children develop breast cancer as a result, this would equate to around 10,000 additional breast cancer cases. We believe this is an unacceptable number of cases which could be avoided at a cost of €43 - €86 million per year.  Breast Cancer UK support strongly the proposed restrictions of BPA in thermal paper as outlined in the Annex XV dossier as a means of helping to protect future generations from an environmental health hazard. |
| **SEAC Rapporteurs response:**  We are grateful for the comments received. We would like to make the following observation and response to the comments.    Regarding the support to extend the restriction to other bisphenols, SEAC would like to clarify that its opinion rather advises to evaluate whether a restriction on BPS is warranted or not if a restriction on BPA is implemented (thus SEAC did not advise that a restriction should necessarily be carried out).  Regarding SEAC’s conclusion that the proposed restriction is unlikely to be proportionate and that ‘break even level of benefits’ is an inappropriate way to assess the effects, no justification is made as to why this is not an appropriate approach.    We note that the comment suggests costs of removing BPA are trivial, whilst costs of health effects are potentially enormous, and that this type of CBA does not take into account the personal costs to those suffering from breast cancer and other impacts. SEAC is of the view that the analysis and opinion assess the evidence on costs and health effects, including personal costs to those suffering from breast cancer. Furthermore we would like to underline that if there was any evidence showing that there would be 10 000 additional cancer cases from exposure to BPA in thermal paper, this would more than offset the costs and the restriction proposal would clearly be proportionate. However, in this case we have evidence of risks for mammary gland changes, and no evidence that any cancer cases would actually occur. Breast Cancer UK does not present evidence that would support that such high incidences (25%) of breast cancer in the population at risk could be conceivable. |
| 285 | **Date/Time:** 2015/11/16 19:32  **Type:** International NGO  **Org. type:**  International NGO  **Org. name:**  ClientEarth  **Org. country:**  United Kingdom  **Company name confidential: No** | **Comments on the SEAC draft opinion:**  ClientEarth welcomes the opportunity to comment on the SEAC draft opinion on the proposed restrictions of Bisphenol A (BPA) in thermal paper.  ClientEarth welcomes SEAC’s analysis of the draft opinion, although it does not agree with the conclusion that that the proposed restriction of BPA in thermal paper is unlikely to be proportionate. ClientEarth would recommend that SEAC avoids using the concept of proportionality when referring to the balance between the costs and benefits of a proposed restriction as it may imply that SEAC is concluding on whether the proposed measure goes beyond what is necessary. This conclusion is cannot be adopted by a scientific committee.  Further, ClientEarth would like to address once again the fact that SEAC did not analyse the draft proposal for a restriction for consumers due to the conclusions of the SEAC that finds BPA adequately controlled for the proposed restriction. However, as the Commission may finally disagree with RAC's conclusions, as well as SEAC's conclusions, a full analysis of costs and benefits would be appropriate.  ClientEarth also agrees that affordability and distributional equity are an important factor in allowing decision makers to conclude on the proportionality of a proposed measure and welcomes SEAC's paragraph detailing these considerations.  Further, on the consideration that BPS is likely to have similar effects of BPA. This hypothesis should not have a decisive influence on assessing the socio-economic benefits of the restriction. A evaluation of the substance is currently ongoing and concluding that substituting to BPS would have little to no benefits, although plausible, would make the evaluation process meaningless.  Therefore ClientEarth suggests that the final opinion does not conclude on proportionality but only summarises the figures on the break even analysis and the possible cost to the EU per capita. Also, the SEAC opinion should recognize that there are uncertainties about BPS as a suitable substitute to BPA due to the ongoing evaluation by the Belgian competent authorities. |
| **SEAC Rapporteurs response:**  We are grateful for the comments received. We would like to make the following observations and responses.    Regarding the comment concerning Proportionality, we refer to our response to CHEM Trust above.  We appreciate the support for considering affordability and distributional equity in the opinion.  Regarding the consideration of BPS, we refer to our previous responses, such as that to the CHEM trust. |
| 289 | **Date/Time:** 2015/11/16 23:56  **Type:** International NGO  **Org. type:**  International NGO  **Org. name:**  Europeam Environmental Bureau (EEB)  **Org. country:**  Belgium  **Company name confidential: No**  **Attachment:** | **Comments on the SEAC draft opinion:**  In conclusion, we agree with RAC and SEAC that EU-wide action is justified to reduce risks.  However,  • We disagree with both committees that the risk to consumers has been shown to be adequately controlled;  • We disagree with SEAC that the proposed restriction is not proportional; and  • We disagree with SEAC’s apparent conclusion that alternative RMOs should be studied.  On the risk to consumers, we have pointed out that  • RAC’s own analysis fails to examine a true worst-case scenario, and even so shows the risks to be marginally controlled at best; and  • all of SEAC’s conclusions follow from a narrow and inappropriately precise interpretation of RAC’s RCRs;  • Given the scientific uncertainty, we do not believe that RAC’s risk characterisation is necessarily more accurate that that of the DS. We are not convinced that SEAC or the Commission is obligated to privilege RAC’s opinion, which did not find a risk to consumers, over the risk characterisation of the DS, which did find such a risk to be strongly uncontrolled risk for multiple endpoints [restriction proposal p216 ].  On proportionality,  • We believe that SEAC’s conclusions are driven largely by cost-benefit assessment, which is only one way of describing proportionality; and further, that proportionality is only one of a number of enumerated criteria for assessing the “most appropriate” RMO;  • As a result, SEAC relies heavily on a simplistic break-even analysis which inappropriately valuates substantial risks to the target population;  • SEAC’s break-even analysis assumed an unreasonable distribution of risks across five endpoints;  • We observe that, in seeking an answer to this question, SEAC informally presented numbers that were far from the best estimate to RAC, and appears to have forced RAC to answer SEAC’s ill-formed question about “concurrent” risks rather than giving a true opinion. Moreover, it appears that SEAC applied RAC’s estimates from one set of values to a very different set of final values.  On alternative RMOs, while SEAC concludes that it does not have enough data on worker-targeted RMOs, we point out that these alternatives are likely to be (a) more expensive and (b) in some cases shift exposures and risks to consumers, which would defeat the goal of defining a narrower RMO.  Finally, we believe that a reopening of the restriction proposal would itself be a non-proportional response to an effective, practical, and monitorable restriction which SEAC estimates would cost on the order of €0.1 - €0.2 per EU citizen per year.  In its implied call for more data on more RMOs, SEAC appears to be demonstrating a textbook case of “paralysis by analysis”, and following the unfortunate approach that it is always easier to ask for more research than to give an opinion that will trigger any decision.  We are also somewhat concerned that SEAC’s opinion overreaches the committee’s mandate to evaluate risks and benefits. In an excellent presentation at the recent “REACH and Beyond” conference, Alexander Nies reiterated a very important point: While describing and attempting to quantify costs and benefits is a technical problem to be undertaken by committees like RAC and SEAC, we must remember that the actual weighing of costs and benefits is inherently a political and social task. While SEAC evaluates costs and benefits, we believe it is the job of the Commission, a political body, to weigh these issues and to evaluate the overall proportionality.  On a more positive note, we stress that the proposed restriction would have important effects on environmental justice and distributional equity, shifting a major burden of BPA use from being a risk of disease in the highest exposed, i.e., primarily in workers, to be absorbed instead in monetary terms by the entire population at the extraordinarily low cost of €0.1 - €0.2 per EU citizen per year. We contend that this small cost is a highly proportionate to the reduction of risk in the exposed population(s).  We point out that market data demonstrates that that acceptable substitutes for BPA are indeed available and being used by industry. We find it telling that that “no comments were received in the public consultation on possible affordability issues for industry.” [SEAC p51].  We again express our concern about SEAC’s use and misuse of numerical precision. It is telling that SEAC submits estimate that are “different” than Table 5, and yet remain “sufficiently similar”, with no documentation of this process whatsoever. Other calculations rely heavily on arbitrary choices like body weight and choice of assessment factor. SEAC’s attention to precision cloaks its conclusions in a false appearance of accuracy. “Precision” and “accuracy” should not be confused.    We do strongly agree with SEAC that any action on BPA should be immediately followed with action on BPS, since the substitution of BPS for BPA is known to be possible but unlikely to reduce risks.  We urge SEAC and the Commission to accept the proposal of the DS, putting in place an effective, low-cost, practical, and monitorable solution that will dramatically reduce risks both to workers and to consumers.  See attached comments for further information |
| **SEAC Rapporteurs response:**  We are grateful for the comments received. We would like to make the following observations and responses to the comments.    SEAC needs to base its assessment on risks established by RAC and thus cannot react to comments regarding RAC’s assessment of risks.  We note the point made that “SEAC’s conclusions are driven largely by cost-benefit assessment”, which is precisely the scope of SEAC’s opinion making remit. We also refer to our response to CHEM Trust for further clarifications on the proportionality assessment.  Regarding the comment that SEAC relies on a simplistic break-even analysis, we are of the view that such an approach provides a scientifically coherent approach used by SEAC on a number of occasions previously. In the absence of any robust dose-response relationships, the remaining options for SEAC to assess the proportionality were limited. This was the reason why SEAC chose to undertake the break-even analysis. EEB did not propose a methodology or concrete suggestions on what it would consider a scientifically appropriate alternative method.  We took note of your objection to the example RMO of glove use amongst workers, and removed this example from the final opinion.  Regarding the assertion that SEAC assumed an unreasonable distribution of risks across endpoints, we fail to understand on what basis this assertion is made. SEAC did not assume a particular distribution of risks, but rather a distribution of costs to be offset by required incidence rates across the different endpoints. In the absence of evidence that one endpoint would be more or less likely than another, SEAC chose an even distribution of the costs across all of the endpoints.  Regarding SEAC’s presentation of incidence estimates to RAC, we have noted the concerns with the approach that was taken and incorporated these into the final opinion, which provides appropriate discussion and consideration of the interpretation of RAC’s response.  Regarding the assertion that SEAC’s calculations rely heavily on arbitrary choices, we would contend that the calculations are transparently based on an examination of the available evidence and literature. Although the calculations may consequently have uncertainties attached to them, this is different to the assertion that they are arbitrary. EEB did not provide concrete suggestions that would enable SEAC to reduce any of the uncertainties in the assessment.  Regarding the consideration of BPS, we refer to our responses above, such as that to the CHEM trust. |